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*Pharmaceuticals, Inc., and Wyeth LLC*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

VALEANT PHARMACEUTICALS  
INTERNATIONAL, INC.; SALIX  
PHARMACEUTICALS, INC.; PROGENICS  
PHARMACEUTICALS, INC.; and  
WYETH LLC, formerly known as WYETH,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC.,  
MYLAN LABORATORIES LTD., and  
MYLAN INC.,

Defendants.

Civil Action No 15-08180 (SRC) (CLW)

*Document Electronically Filed*

**AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Valeant Pharmaceuticals International, Inc. (“Valeant”), Salix Pharmaceuticals, Inc. (“Salix”), Progenics Pharmaceuticals, Inc. (“Progenics”), and Wyeth LLC (collectively, “Plaintiffs”) by way of Amended Complaint against Defendants Mylan Pharmaceuticals, Inc. (“Mylan Pharmaceuticals”), Mylan Laboratories Ltd. (“Mylan Labs”), and Mylan Inc. (collectively, “Mylan” or “Defendants”) allege as follows:

### **THE PARTIES**

1. Plaintiff Valeant is a corporation organized and existing under the laws of Canada. Its United States headquarters are located at 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.

2. Plaintiff Salix is a corporation organized and existing under the laws of California having its principal place of business at 8510 Colonnade Center Drive, Raleigh, NC 27615. Salix is the registered holder of approved New Drug Application No. 021964, which covers Relistor<sup>®</sup>.

3. Plaintiff Progenics is a corporation organized and existing under the laws of Delaware having its principal place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591.

4. Plaintiff Wyeth LLC, formerly Wyeth, is a Delaware LLC, having places of business at 235 East 42nd Street, New York, NY 10017, and Five Giralda Farms, Madison, NJ 07940.

5. Upon information and belief, Defendant Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. Upon information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc. and an agent or affiliate of Mylan Labs.

6. Upon information and belief, Defendant Mylan Labs is a corporation organized and existing under the laws of India, having a place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India. Upon information and belief, Mylan Labs is a wholly-owned subsidiary of Mylan Inc. and an agent or affiliate of Mylan Pharmaceuticals.

7. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 1000 Mylan Blvd., Canonsburg, PA 15317.

### **NATURE OF THE ACTION**

8. This is an action for infringement of United States Patent Nos. 8,247,425 (“the ’425 patent”); 8,420,663 (“the ’663 patent”); 8,552,025 (“the ’025 patent”); 8,822,490 (“the ’490 patent”); and 9,180,125 (“the ’125 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Mylan’s filing of an Abbreviated New Drug Application (“ANDA”) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market its generic methylnaltrexone bromide formulation for subcutaneous injection, 12 mg/0.6 mL (“Mylan’s generic methylnaltrexone bromide formulation for subcutaneous injection”).

### **JURISDICTION AND VENUE**

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. Upon information and belief, this court has jurisdiction over Mylan Pharmaceuticals. Upon information and belief, Mylan Pharmaceuticals is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Pharmaceuticals directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan’s generic methylnaltrexone bromide formulation for subcutaneous injection. Upon information and belief, Mylan Pharmaceuticals is registered to do business in New Jersey and purposefully has

conducted and continues to conduct business in this judicial district.

11. Upon information and belief, this court has jurisdiction over Mylan Labs. Upon information and belief, Mylan Labs is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Labs directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection. Upon information and belief, Mylan Labs purposefully has conducted and continues to conduct business in this judicial district.

12. Upon information and belief, this court has jurisdiction over Mylan Inc. Upon information and belief, Mylan Inc. is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Inc. directly, or indirectly, manufactures, markets, and sells generic drug products, including generic products manufactured by Mylan Pharmaceuticals and/or Mylan Labs, throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection. Upon information and belief, Mylan Inc. is registered to do business in New Jersey and purposefully has conducted and continued to conduct business in this judicial district.

13. Upon information and belief, Mylan Pharmaceuticals is registered to do business in New Jersey under business ID 0100214227, is registered as a drug manufacturer and wholesale drug distributor under registration number 5003762, and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ 08628, as its registered agent for the receipt of service of process.

14. Upon information and belief, Mylan Inc. is registered to do business in New Jersey under business ID 0100971292 and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ 08628, as its registered agent for the receipt of service of process.

15. Mylan Pharmaceuticals and Mylan Inc. avail themselves of the rights, benefits, and privileges of this Court by filing complaints in the District of New Jersey: *Mylan Pharmaceuticals, Inc. v. Celgene Corporation*, Civil Action No. 2:14-cv-02094; and *Mylan Inc. et al. v. Apotex Inc. et al.*, Civil Action No. 3:14-cv-04560.

16. Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc. consented to or did not contest the jurisdiction of this Court in at least the following District of New Jersey actions: *Baxter Healthcare Corp. et al. v. Agila Specialties Private Limited et al.*, Civil Action No. 1:14-cv-07094 (Mylan Pharmaceuticals and Mylan Labs); *Horizon Pharma, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 3:15-cv-03327 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); *Astrazeneca AB et al. v. Mylan Pharmaceuticals Inc. et al.*, Civil Action No. 3:13-cv-04022 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); and *Janssen Products, L.P. et al. v. Lupin Limited et al.*, Civil Action No. 2:10-cv-05954 (Mylan Pharmaceuticals and Mylan Inc.).

17. Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc. availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims in at least the following prior District of New Jersey actions: *Baxter Healthcare Corp. et al. v. Agila Specialties Private Limited et al.*, Civil Action No. 1:14-cv-07094 (Mylan Pharmaceuticals and Mylan Labs); *Horizon Pharma, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 3:15-cv-03327 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); *Astrazeneca AB et al. v. Mylan*

*Pharmaceuticals Inc. et al.*, Civil Action No. 3:13-cv-04022 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); and *Janssen Products, L.P. et al. v. Lupin Limited et al.*, Civil Action No. 2:10-cv-05954 (Mylan Pharmaceuticals and Mylan Inc).

18. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

### **THE PATENTS IN SUIT**

19. The U.S. Patent and Trademark Office (“PTO”) issued the ’425 patent on August 21, 2012. The ’425 patent claims, *inter alia*, prefilled syringes comprising liquid compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the ’425 patent and have the right to sue for infringement thereof. A copy of the ’425 patent is attached hereto as Exhibit A.

20. The PTO issued the ’663 patent on April 16, 2013. The ’663 patent claims, *inter alia*, methods of using compositions of methylnaltrexone. Plaintiffs hold all substantial rights in the ’663 patent and have the right to sue for infringement thereof. A copy of the ’663 patent is attached hereto as Exhibit B.

21. The PTO issued the ’025 patent on October 8, 2013. The ’025 patent claims, *inter alia*, pharmaceutical preparations of methylnaltrexone. Plaintiffs hold all substantial rights in the ’025 patent and have the right to sue for infringement thereof. A copy of the ’025 patent is attached as Exhibit C.

22. The PTO issued the ’490 patent on September 2, 2014. The ’490 patent claims, *inter alia*, packaged compositions comprising liquid compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the ’490 patent and have the right to sue for infringement thereof. A copy of the ’490 patent is attached hereto as Exhibit D.

23. The PTO issued the '125 patent on November 10, 2015. The '125 patent claims, *inter alia*, compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '125 patent and have the right to sue for infringement thereof. A copy of the '125 patent is attached hereto as Exhibit E.

24. Salix is the holder of New Drug Application ("NDA") No. 021964 for Relistor<sup>®</sup>. In conjunction with NDA No. 021964, the '425 patent, '663 patent, '025 patent, '490 patent, and '125 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

25. Methylnaltrexone bromide formulations for subcutaneous injection, 8 mg/0.4 mL and 12 mg/0.6 mL, are sold in the United States under the trademark Relistor<sup>®</sup>.

#### **MYLAN'S INFRINGING ANDA SUBMISSION**

26. Upon information and belief, Mylan filed or caused to be filed with the FDA ANDA No. 208-592, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

27. Upon information and belief, Mylan's ANDA No. 208-592 seeks FDA approval to sell in the United States Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection, intended to be a generic version of Relistor<sup>®</sup>.

28. Salix, Progenics and Wyeth LLC received a letter from Mylan Pharmaceuticals dated October 6, 2015, purporting to be a Notice of Certification for ANDA No. 208-592 ("Mylan's first notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c). Mylan's notice letter was addressed to Wyeth LLC at Madison, NJ.

29. Salix, Progenics and Wyeth LLC received a letter from Mylan Pharmaceuticals dated December 23, 2015, purporting to be a Notice of Certification for ANDA No. 208-592

(“Mylan’s second notice letter”) under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C.

§ 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c). Mylan’s second notice letter was addressed to Wyeth LLC at Madison, NJ.

30. Mylan’s second notice letter states that “Mylan Pharmaceuticals Inc. is the authorized U.S. Agent for the Applicant Mylan Laboratories Limited” with respect to ANDA No. 208-592 as well as related ANDA No. 208-594. Mylan’s second notice letter refers to Mylan Pharmaceuticals and Mylan Labs collectively as “Mylan.”

31. Mylan’s first notice letter and second notice letter allege that Mylan has submitted to the FDA ANDA No. 208-592 seeking FDA approval to sell Mylan’s generic methylnaltrexone bromide formulation for subcutaneous injection, intended to be a generic version of Relistor<sup>®</sup>.

32. Mylan’s first notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of claims 1-23 of the ’025 patent, claims 1-11 and 13-27 of the ’663 patent, and claims 1-24 and 27-61 of the ’490 patents.

33. Mylan’s second notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of claims 1-12 and 20 of the ’125 patent.

34. Upon information and belief, ANDA No. 208-592 seeks approval of Mylan’s generic methylnaltrexone bromide formulation for subcutaneous injection that is the same, or substantially the same, as Relistor<sup>®</sup>.

35. Upon information and belief, Mylan Pharmaceuticals’ actions relating to ANDA No. 208-592 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Mylan Inc.

**COUNT I AGAINST MYLAN**

**Infringement of the '425 Patent under § 271(e)(2)**

36. Paragraphs 1-35 are incorporated herein as set forth above.

37. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '425 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208-592 seeking approval for the commercial marketing of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration date of the '425 patent.

38. Upon information and belief, Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will, if approved and marketed, infringe at least one claim of the '425 patent.

39. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '425 patent.

**COUNT II AGAINST MYLAN**

**Declaratory Judgment of Infringement of the '425 Patent**

40. Paragraphs 1-39 are incorporated herein as set forth above.

41. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

42. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

43. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone

bromide formulation for subcutaneous injection before the expiration date of the '425 patent, including Mylan's filing of ANDA No. 208-592.

44. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '425 patent.

45. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will constitute infringement of at least one claim of the '425 patent.

### **COUNT III AGAINST MYLAN**

#### **Infringement of the '663 Patent under § 271 (e)(2)**

46. Paragraphs 1-45 are incorporated herein as set forth above.

47. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '663 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208-592 seeking approval for the commercial marketing of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '663 patent.

48. Upon information and belief, Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will, if approved and marketed, infringe at least one claim of the '663 patent.

49. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '663 patent.

**COUNT IV AGAINST MYLAN**

**Declaratory Judgment of Infringement of the '663 Patent**

50. Paragraphs 1-49 are incorporated herein as set forth above.

51. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

52. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

53. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration date of the '663 patent, including Mylan's filing of ANDA No. 208-592.

54. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '663 patent.

55. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will constitute infringement of at least one claim of the '663 patent.

**COUNT V AGAINST MYLAN**

**Infringement of the '025 Patent under § 271(e)(2)**

56. Paragraphs 1-55 are incorporated herein as set forth above.

57. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '025

patent by submitting, or causing to be submitted to the FDA, ANDA No. 208-592 seeking approval for the commercial marketing of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '025 patent.

58. Upon information and belief, Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will, if approved and marketed, infringe at least one claim of the '025 patent.

59. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection, directly infringe and/or contributorily infringe at least one claim of the '025 patent.

#### **COUNT VI AGAINST MYLAN**

##### **Declaratory Judgment of Infringement of the '025 Patent**

60. Paragraphs 1-59 are incorporated herein as set forth above.

61. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

62. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

63. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration date of the '025 patent, including Mylan's filing of ANDA No. 208-592.

64. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone bromide formulation for

subcutaneous injection will directly infringe and/or contributorily infringe at least one claim of the '025 patent.

65. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will constitute infringement of at least one claim of the '025 patent.

#### **COUNT VII AGAINST MYLAN**

##### **Infringement of the '490 Patent under § 271(e)(2)**

66. Paragraphs 1-65 are incorporated herein as set forth above.

67. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '490 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208-592 seeking approval for the commercial marketing of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '490 patent.

68. Upon information and belief, Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will, if approved and marketed, infringe at least one claim of the '490 patent.

69. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '490 patent.

#### **COUNT VIII AGAINST MYLAN**

##### **Declaratory Judgment of Infringement of the '490 Patent**

70. Paragraphs 1-69 are incorporated herein as set forth above.

71. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

72. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

73. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration date of the '490 patent, including Mylan's filing of ANDA No. 208-592.

74. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '490 patent.

75. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will constitute infringement of at least one claim of the '490 patent.

#### **COUNT IX AGAINST MYLAN**

##### **Infringement of the '125 Patent under § 271(e)(2)**

76. Paragraphs 1-75 are incorporated herein as set forth above.

77. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '125 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208-592 seeking approval for the commercial marketing of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration date of the '125 patent.

78. Upon information and belief, Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will, if approved and marketed, infringe at least one claim of the '125 patent.

79. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '125 patent.

### **COUNT X AGAINST MYLAN**

#### **Declaratory Judgment of Infringement of the '125 Patent**

80. Paragraphs 1-79 are incorporated herein as set forth above.

81. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

82. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

83. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration date of the '125 patent, including Mylan's filing of ANDA No. 208-592.

84. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '125 patent.

85. Plaintiffs are entitled to a declaratory judgment that future commercial

manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection will constitute infringement of at least one claim of the '125 patent.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs respectfully request that the Court enter judgment in their favor and against Mylan on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '425 patent by submitting or causing to be submitted ANDA No. 208-592 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '425 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '663 patent by submitting or causing to be submitted ANDA No. 208-592 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '663 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '025 patent by submitting or causing to be submitted ANDA No. 208-592 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '025 patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one

claim of the '490 patent by submitting or causing to be submitted ANDA No. 208-592 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '490 patent;

5. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '125 patent by submitting or causing to be submitted ANDA No. 208-592 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '125 patent;

6. order that that the effective date of any approval by the FDA of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection be a date that is not earlier than the expiration of the '425 patent, '663 patent, '025 patent, '490 patent, and the '125 patent or such later date as the Court may determine;

7. enjoin Mylan from the commercial manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection until expiration of the '425 patent, '663 patent, '025 patent, '490 patent, and the '125 patent or such later date as the Court may determine;

8. enjoin Mylan and all persons acting in concert with Mylan from seeking, obtaining, or maintaining approval of Mylan's ANDA No. 208-592 until expiration of the '425 patent, '663 patent, '025 patent, '490 patent, and the '125 patent;

9. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees;

10. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: February 4, 2016  
Newark, New Jersey

Respectfully submitted,

s/ Elvin Esteves

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s/ Elvin Esteves

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**CERTIFICATION OF NON-ARBITRABILITY**  
**PURSUANT TO LOCAL CIVIL RULE 201.1(d)**

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the statements made by me are willfully false, I am subject to punishment.

Dated: February 4, 2016  
Newark, New Jersey

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